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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/677,877

10/02/2003

Peng Liang

03-052-PL

9984

7590

05/31/2006

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EXAMINER

ROOKE, AGNES BEATA

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/677,877	<b>Applicant(s)</b> LIANG, PENG	
	<b>Examiner</b> Agnes B. Rooke	<b>Art Unit</b> 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 4, 5 and 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 6-14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's election without traverse of Group I, claims 1-3 and 6-14 in the reply filed on 03/21/2006 are acknowledged.

Claims 1-19 are pending. Claims 1-3 and 6-14 are currently under examination. Claims 4, 5, and 15-19 are withdrawn from further examination because they refer to non-elected subject matter. Therefore, the restriction requirement is proper and it is made FINAL.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Objection to Specification***

In the specification, a proper designation for sequence number must be assigned as: "SEQ ID NO:"

Through the specification there are typographical errors, for example, on page 3, line 18, and page 14, line 22, the square symbols must be removed. Also, the ending paragraph on page 14 does not have a period.

### ***Objection to Claims***

In claim 3, there is a typographical error in the first line of the claim.

In claims 6-10, the non-elected subject matter must be deleted.

In claims 11 and 14, the proper sequence identification number should be designated as "SEQ ID NO:"

Claim 8 is missing the space after the word "claim."

Claims 6-14 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, claims 6-14 have not been further treated on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Vuorio et al. (WO 97/17988).

Vuorio et al. teach in claims 1-7, on page 27, and in Brief Description of the Drawings on page 4, a fusion collagen, where using a method comprising culturing host cells transformed with recombinant DNA expression vector; and recovering the fusion protein from the cell culture; where different host cells, such as yeast or insect cells are used; see page 9, lines 3-10.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gruber et al. U.S. 6,617,431 (PCT publication date June 28, 1998). See Abstract.

The Abstract of Gruber et al. teach the use of a recombinant nucleotide sequence containing a cDNA coding for one or several mammal collagen chains or derived proteins and elements enabling a plant cell to produce the collagen chain(s) or derived proteins, coded by said cDNA, particularly a transcription promoter and terminator identified by the transcription machinery of the plant cells, for transforming the plant cells so as to obtain from these cells, or plants obtained from them, the collagen chain(s) or derived proteins.

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to design a method to generate a secreted trimeric fusion protein, such as collagen, because a method of creating a DNA comprising a sequence of choice, and introducing that DNA construct into a host cell, and growing a host cell in a medium, and isolating a protein of interest, is known in the prior art as disclosed by the Abstract of Gruber et al.

One would be motivated to design the instant method of generating different collagen fusion proteins because different protein combinations could be created by that method, such as trimeric collagen, for example.

Further, the end effect of using eukaryotic cells as host cells in the instant method instead of plant cell as disclosed in Gruber et al., would have the same end effect of achieving desired fusion proteins.

Art of record:

McAlinden et al.,  $\alpha$ -Helical coiled-coil oligomerization domains are almost ubiquitous in the collagen superfamily, The Journal of Biological Chemistry, 2003, 278, 43, p. 42200-42207, teach different fusion constructs of cDNA encoding the full length human type IIA pro-collagen N-propetide linked to amino acids of the coiled-coil domain present at the beginning of the type II procollagen C-propetide (see page 42201, left column, last paragraph); where the Chinese hamster ovary cells were transfected with the cDNA fusion constructs; where the host cells grow in the medium; and then where the proteins were collected (see page 42201, right column, second paragraph).

***Conclusion***

The USPTO search engine GenCore version 5.1.7 found other sequences in the prior art that have 99.3% identity to the SEQ ID NO:1 and 2 of the instant invention.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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